UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,974	02/08/2002	Lhing-Yew Li		3799

45453 7590 03/14/2005

BUCHANAN INGERSOLL PC
(ARCHER DANIELS MIDLAND COMPANY)
301 GRANT STREET, 20TH FLOOR
PITTSBURGH, PA 15219

EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,974	LI ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-42* is/are pending in the application.

4a) Of the above claim(s) *24 and 40-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-23 and 25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *ENZYME 2.6.1.17*.

DETAILED ACTION

Application Status

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on December 7, 2004 has been entered.

2. In response to the previous Office action, a final Office action (mailed on September 8, 2004), Applicants filed response, including an RCE, and amendment received on December 7, 2004. Said amendment amended Claims 1-4, 7-13, 15, 20 and 25-29 and added new Claims 30-42. Thus, Claims 1-13 and 15-242 are pending in the instant Office action.

Restriction/Election

3. Restriction to one of the following inventions was required under 35 U.S.C. § 121 in the Office action mailed November 10, 2003:

I. Claims 1-23, 25 (and new Claims 26-39 and 41), drawn to polynucleotide molecules, related products and methods, classified in class 435, subclass 471.
II. Claim 24, drawn to methods of producing lysine, classified in class 435, subclass 115.

Based on newly filed claims, restriction is additionally required under 35 U.S.C. § 121 as follows:

III. Claim 40, drawn to lysine, classified in class 562, subclass 561.
IV. Claim 41, drawn to an ORF2 polynucleotide, classified in class 536, subclass 23.2.
V. Claim 42, drawn to an ORF2 polypeptide, classified in class 435, subclass 232.

4. The inventions are distinct, each from the other because of the following reasons:

The reasons for Group I and Group II distinction is as noted in the original restriction requirement.

Group I is related to Group III by virtue of the fact that the polynucleotides encodes proteins that produce lysine, the product of Group III. However, polynucleotides and lysine have wholly distinct structures and functions. Thus, Groups I and III are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups I and III have been properly restricted as distinct inventions burdensome to be searched together.

Groups I and IV are related as polynucleotides having a same, generic structure of all polynucleotides, repeating nucleotide units. However, these products are distinct because they have wholly distinct structures and functions. The structures of Group I and IV are distinct based on the distinct SEQ ID NOs related to them. The functions are distinct because they encode different enzymes. Thus, Groups I and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups I and IV have been properly restricted as distinct inventions burdensome to be searched together.

The polynucleotides of Group I are related to the proteins of Group V by virtue of the fact that the polynucleotides can encode the enzyme. The polynucleotide molecule has utility for the recombinant production of the enzyme in a host cell. Although the polynucleotides and the

enzymes are related, they are distinct inventions because they are wholly different in structure and function. A polynucleotide's structure is comprised of linear, contiguous nucleotides while an enzyme's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the polynucleotide's function is to encode a protein while an enzyme's function is variable, and in this case, having thymidilate (sic) synthase activity. Therefore, Group I is patentably distinct from Group V. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group V, restriction for examination purposes as indicated is proper. While Groups I and Groups V can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group V, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups I and V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, lysine can be made by a materially different process of producing the product, such as

purification from a natural, non-recombinant source. Thus, Groups II and III are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups II and III have been properly restricted as distinct inventions burdensome to be searched together.

Group II is related to Group IV by virtue of the disclosure describing them as useful together. However, the polynucleotide of Group IV is not used in the methods of Claim 24, nor is it made by said methods. Thus, Groups II and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups II and IV have been properly restricted as distinct inventions burdensome to be searched together.

Groups II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being used together since the methods of Claim 24 use a polynucleotide not necessarily encoding ORF2 polypeptide. Thus, the function of the method is wholly distinct from the function of the ORF2 polypeptide, and Group II is patentably distinct from Group V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups II and V have been properly restricted as distinct inventions burdensome to be searched together.

Groups III-V are related by virtue of the disclosure that their products may be used and/or made together. However, each of the groups are wholly distinct in structure and function. Lysine is a small molecule, a polynucleotide is repeating units of nucleotides, and a polypeptide is repeating units of amino acids. Moreover, all their functions are distinct as evidenced by the specification and above. Thus, Groups III-V are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Thus, Groups III-V have been properly restricted as distinct inventions burdensome to be searched together.

5. Newly submitted claims 40-42 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons noted above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40 and 42 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

6. Claims 1-13 and 15-42 are pending. Claims 24 and 40-42 are withdrawn from further consideration as non-elected inventions; Claim 24 remains subject to rejoinder as a method of using the elected product. Claims 1-13, 15-23, and 25-39 will be examined herein.

Priority

7. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/267,183 filed on February 8, 2001.

In contrast to the Examiner's previous indication, Claim 1 (amended most recently to the subject matter of Claim 25 previously pending) does ***not*** have support in the provisional application. The provisional application is directed to KDBH polynucleotides, and Claim 1 of the instant application is a KDB polynucleotide (not including encoding diaminopimelate dehydrogenase or ddh or H). Dependent claims requiring the ddh polynucleotide portion might have support back to the provisional and are analyzed as follows:

a) Claim 2 lacks support in the provisional because the only mention of 80% identical is with respect to polypeptide embodiments and not in relation to the KDBH polynucleotides.
b) None of Claims 3-8, 10-12, 15-23, 25-38 mention ddh as an added limitation as found in the provisional application - Claim 3, not at all; Claim 4, only optionally.
c) Claim 9 does not require the ddh as found in the provisional.
d) Claim 39 includes both KDBH and KDB vectors so lacks support in the provisional.
e) Alternatively, Claim 13 requires a ddh encoding polynucleotide as limited to in the provisional and is granted the earlier date of February 8, 2001 for prosecution in the instant Office action.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

8. Previous rejection of Claim 20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the inclusion of *Brevibacterium lactofermentum* and *Corynebacterium glutamicum* in the Group is withdrawn by virtue of Applicant's amendment to the genus *Corynebacterium*.

Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

9. Previous rejection of Claim 25 under 35 U.S.C. § 112, second paragraph, for the term "N-succinylaminoketopimelate transaminase (dapC)" is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the activity named adequately describes the dapC gene product. However, this is not the basis of the rejection. For the instant rejection, it is unclear what the named activity is. Applicant further argues that the affidavit submitted by Inventor Li describes the definiteness of the term. In said affidavit, Inventor Li declares that the art clearly defines the term as evidenced by Hartmann *et al.* (2003 - post-filing date). In Hartmann *et al.*, dapC is described as succinyl-aminoketopimelate transaminase (EC 2.6.1.17) (see Figure 1 on page 200); however, this enzyme name is inconsistent with the enzyme name(s) assigned this EC number in the nomenclature. The names for E.C. 2.6.1.17 are succinyldiaminopimelate transaminase or succinyldiaminopimelate aminotransferase or N-succinyl-L-diaminopimelic glutamic transaminase (see attachment). Thus, as previously noted, the activity of succinyl-aminoketopimelate transaminase is unclear, particularly in consideration of the prior art.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

10. All previous rejections of claims under 35 U.S.C. § 112, first paragraph, written description (lack of structure and function) are herein withdrawn and, where necessary, are reapplied below. Applicant argues that the functionality of ORF2 polypeptide as inserted into the claims overcomes the instant rejection. While this is the case, in part, for rejections of the ORF2 polypeptide lacking function, other rejections based on fragment language lacking function, etc. are not overcome by the amendment.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

11. Previous rejection of Claims 7, 9-11, and 26-29 under 35 U.S.C. § 112, first paragraph, written description, based on the limitation of being "native to … *Corynebacterium*" is herein maintained and amended to be based on the language "from a cell of the genus *Corynebacterium*". Applicant presents no arguments specifically set forth concerning the instant rejection.

As noted below in a new rejection under 35 U.S.C. § 112, second paragraph, the phrase "from a cell of the genus *Corynebacterium*" can have two different meanings, one of which is equivalent to the phrase native to … *Corynebacterium*. Thus, the amendment does not overcome the instant rejection as previously set forth:

> "To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.
>
> In the specification, a single example of an ask, ddh, ORF2, and lysA from coryneform that meets the limitations of the instant claims is described. No examples of other coryneform sequences are described, either ask, ddh, ORF2, and lysA sequences or general coryneform sequences. The instant claims are drawn to a *subgenus* of all ask, ddh, ORF2, and lysA genes within the claimed structural limitations, wherein the DNA must be from coryneform. The specification does not describe coryneform ask, ddh, ORF2, and lysA sequences to the exclusion of ask, ddh, ORF2, and lysA sequences from other sources. Clearly, ask, ddh, ORF2, and lysA sequences from coryneform within the structural limitations are enabled by the disclosure; however, one of skill in the art would be unable to recognize other members of the claimed subgenus to the exclusion of, for example, ask, ddh, ORF2, and lysA genes from *E. coli*, within the structural limitations. Thus, the claimed subgenus does not have adequate written description."

Withdrawn - Claim Rejections - 35 U.S.C. § 102

12. Previous rejection of Claim 13 under 35 U.S.C. § 102(a) as being anticipated by Li *et al.* (WO 01/49854 – see IDS) is withdrawn. Li *et al.* is not considered prior art since Claim 13 can be granted priority to February 8, 2001 since Claim 13 is fully supported by the provisional application as noted above.

13. Previous rejection of Claims 3, 5, 6, and 10 under 35 U.S.C. § 102(a) as being anticipated by Li *et al.* (WO 01/49854 – see IDS) is withdrawn. With the negative limitation added to Claim 1, Hanke *et al.* no longer teach all the limitations, nor can said limitations be rendered obvious because of the lack of disclosure of Hanke *et al.* about general exclusion of dapA from the gene constructs.

14. Previous provisional rejection of Claims 3 and 10 under 35 U.S.C. 102(e) as being anticipated by Hanke *et al.* (U.S. Application 09/722,441, now allowed) is withdrawn. With the negative limitation added to Claim 1, Hanke *et al.* no longer teach all the limitations, nor can said limitations be rendered obvious because of the lack of disclosure of Hanke *et al.* about general exclusion of dapA from the gene constructs.

Maintained - Claim Rejections - 35 U.S.C. § 102

15. Previous rejection of Claims 1, 2, 4, 7-9, 11-12, 15-23 under 35 U.S.C. § 102(a) as being anticipated by Hanke *et al.* (WO 01/49854, published July 12, 2001 – see IDS) is maintained; Claims 25-38 are added herein. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that WO 01/49854 is not available under 35 U.S.C. § 102(a) because of the right of the instant claims to be granted priority to the provisional application filed February 8, 2001. However, due to the lack of granting of priority to Claims 1-12 and 15-23 to the provisional document 60/267,183 (see above in Priority section), WO 01/49854 is available under 35 U.S.C. § 102(a) as of its publication date of July 12, 2001, which is prior to the filing date of the instant application of February 8, 2002 by less than a year.

To reiterate by virtue of the amendments to the claims, Hanke *et al.* (WO 01/49854) teach several combinations of polynucleotides encoding the following:

aspartate kinase (ask or K),
aspartate-semialdehyde dehydrogenase (asd or D),
dihydrodipicolinate reductase (dapB or B),
diaminopimelate dehydrogenase (ddh or H),
ORF2 (no abbreviations used),
diaminopimelate decarboxylase (lysA or L), and
dihydrodipicolinate synthase (dapA or A).

The sources of the polynucleotides in Hanke *et al.* are set forth on page 46. While Hanke *et al.* teach various combinations of the above genes, Hanke *et al.* do not teach general exclusion of dapA, which exclusion is required in Claim 1 (not comprising dihydrodipicolinate synthase).

Hanke *et al.* also teach using the P1 promoter (see page 62, example 7), which is not a novel promoter.

In the Examples, Hanke *et al.* teach numerous expressly made constructed that contain the above genes. Those that at least meet the limitations of Claim 1 are only pFC1-ask-asd-dapB-ddh-lysA (see page 65, number 9) and pDElia2$_{FC5}$-ask-asd-dapB-ddh-lysA (see page 65, number 8). Hanke *et al.* teach their vectors in host cells, namely *E. coli, Corynebacterium, C. glutamicum, B. flavum, B. lactofermentum*, and specific deposits thereof as well as other

nonhuman host cells, which include prokaryotes and eukaryotes (see page 8). Hanke *et al.* teach their methods by insertion of their vectors into a host cell's chromosome or retaining said vectors extra-chromosomally (see page 24). Hanke *et al.* also teach the specific vectors and control regions of Claims 37-38 (see pages 39-40).

16. Previous provisional rejection of Claims 1, 2, 4, 7-9, 11-13, 15-23 under 35 U.S.C. 102(e) as being anticipated by Hanke *et al.* (U.S. Application 09/722,441, now allowed) is maintained. Applicant's arguments have been fully considered but are not deemed persuasive.

Applicant argues Hanke *et al.* do not teach the claims as amended. As noted above in the analogous rejection using WO 01/49854 (U.S. Application 09/722,441 is the national stage entry (371) of WO 01/49854), Hanke *et al.* do teach all the limitations of the instant claims. Claim 13 is included (in contrast to the above rejection) because priority to the provisional document (filed February 8, 2001) does not overcome the instant rejection since 09/722,441 was filed on November 28, 2000.

NEW ISSUES

Objections to the Specification

17. The amendment filed December 7, 2004 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "thymidilate synthase or 2,3-dihydrodipicolinate N-C6-lyase activity" as found in non-elected Claims 41-42. See also new matter rejection under 35 U.S.C. § 112, first paragraph, below.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

18. Claim 4 is objected to for the plural "polypeptides" in line 4. Neither of the preceding two "complete or truncated" phrases are followed by a plural form of the polypeptide. Thus, consistency and proper English dictate that this term be singular. Correction is required.

19. Claims 17-19 are objected to for having inconsistent use of language and antecedent indicating language. In Claim 17, "said vector" should be ---the vector---. In Claim 18, "said cell" should be ---said host cell--- as found in other, similar claims. In Claim 19, "the cell" should be ---said host cell--- as found in other, similar claims. These corrections, or others to improve the consistency of the claims, are required.

20. Claim 30 is objected to for the comma after the first NRRL number; only two members are joined by "and" alone. Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 1-13, 15-24, and 26-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, the term "N-succinylaminoketopimelate transaminase (dapC)" is unclear as maintained above for Claim 25. Clarification is required.

22. Claims 4-6, 11, 15, 29, and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 4, the language "optionally…optionally…and" is unclear. It is wholly unclear which items are required as claim limitations which are not. The language is arduous and difficult to understand. The Examiner suggests itemization (a, b, etc.) and/or indentation to help clarify exactly what is being claimed. Clarification is required.

23. Claims 5-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 5, the phrase "comprises **a** P1 promoter element of SEQ ID NO:15" (emphasis added) is unclear. With the language as written, "a P1 promoter element" indicates that any portion of SEQ ID NO:15 that is a promoter element is included. However, the disclosure does not teach portion of SEQ ID NO:15 that function as promoters but only teach the entirety of SEQ ID NO:15 that functions as such. Thus, it is unclear if a promoting portion of SEQ ID NO:15 is intended (as literally claimed presently) or if the use of the entire SEQ ID NO:15 is intended as indicated in the specification. If the latter, the Examiner suggests --- comprises the P1 promoter element as set forth in SEQ ID NO:15--- for clarity.

24. Claims 7, 9-11, and 26-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 7 and 9-11, the phrase "from a cell of the genus *Corynebacterium*" is unclear. Due to the recombinant nature of the art and the instant specification, any gene can be introduced into *Corynebacterium* and then retrieved rendering

said gene "from *Corynebacterium*". Thus, with the instant phrase, it is unclear if the gene is native to *Corynebacterium* or if the gene intended is any gene that can be transformed into *Corynebacterium*. Clarification is required.

25. Claims 26-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In each of said claims, the antecedent basis of "said bacterium" is unclear since none of Claims 7 and 9-11 claim anything to do with a generic bacterium. Clarification is required.

26. Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In said claim, the antecedent basis of the phrase "said vector" is unclear. Claim 16 is drawn to a vector comprising a particular polynucleotide. From the language of Claim 37, it is unclear if the named vectors already contain the required polynucleotide or not. Clarification is required. The Examiner suggests rewriting the claim to depend from Claim 1 directly saying ---A vector comprising the isolated polynucleotide of Claim 1 and a vector selected from the group consisting of...--- for clarity.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

27. Claims 2-6, 8-11, and 27-30 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claims 2, 4, and 8, the limitation of a polynucleotide encoding a polypeptide having at least 80% identity to SEQ ID NO:8 or 12 or 2 or 4 is not supported in the specification as originally filed. Applicant notes that support is found in paragraph [0074]; the Examiner finds none here. In paragraph [0066], recitation of 80% as related to expressed polypeptides; no where in this citation is this limitation linked to the invention of the KDB polynucleotides. Thus, the 80% limitation is considered new matter. Applicant is required to delete the new matter or cite clear support (page and line number) where support can be found.

28. Claims 3-6, 10, 11, 15, 28, 29, and 30 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claims 3 and 4, the limitation of having "thymidilate synthase or 2,3 dihydrodipicolinate N-C6-lyase activity" is not supported by the instant specification or the claimed provisional. Applicant notes that support is found in a declaration filed on Inventor Li; however, support must be found in the originally filed specification. Applicant is required to delete the new matter or cite clear support (page and line number) where support can be found in the specification as originally filed.

29. Claim 25 is rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of not comprising polynucleotides encoding any (i.e., all) of 5 enzymes is not supported. The only support of any recitation of these enzyme names the examiner can find is in original Claim 25, which in no way indicates not having all of the enzymes. Applicant is required to delete the new matter or cite clear support (page and line number) where support can be found.

30. Claims 2-6, 9-11, 13, 15, 27-29, 30 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 is drawn to a polynucleotide molecule additionally comprising (optionally) a **truncated ddh polypeptide** having at least 80% identity with SEQ ID NO:8. Thus, Claim 2 has a claim limitation with structural language in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which

is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification teaches a polynucleotide encoding diaminopimelate dehydrogenase (ddh or H) as SEQ ID NO:7 wherein SEQ ID NO:8 is the encoded amino acid (see Figure 5 description in paragraph [0013]). The specification has fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations (i.e., having diaminopimelate dehydrogenase activity). However, the genus of the instant claims also contains polynucleotides within the sequence percent identity limitations, but having different function since a truncated ddh is no longer required to have ddh activity. The specification has not fully described a genus that has sequence percent identity limitations in the absence of functional limitations.

31. Claims 3-6, 10, 11, 15, 28-30 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3 is drawn to a polynucleotide molecule additionally comprising (optionally) a **truncated ORF2 polypeptide** encoded by a polynucleotide having at least 90% identity with SEQ ID NO:9 and at least 25% of

the full length ORF2. Thus, Claim 3 has a claim limitation with structural language in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held as noted above.

The instant specification teaches a polynucleotide encoding ORF2 as SEQ ID NO:9 wherein SEQ ID NO:10 is the encoded amino acid (see Figure 6 description in paragraph [0014]). The specification also teaches a particular truncated form of ORF2 that is SEQ ID NO:14, which is encoded by SEQ ID NO:13 (see Figure 8 description in paragraph [0016]). The specification has fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations (i.e., having some ORF2 activity). However, the genus of the instant claims also contains polynucleotides within the sequence percent identity limitations and fragment limitations, but having different function since a truncated ORF2 is no longer required to have the ORF2 activity named in Claim 3. The specification has not fully described a genus that has sequence percent identity and/or fragment limitations in the absence of functional limitations.

32. Claims 4-6, 11, 15, 29, 30 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 4 is drawn to a polynucleotide molecule additionally comprising (optionally) a **truncated diaminopimelate decarboxylase polypeptide** (lysA or L) having at least 80% identity with SEQ ID NO:12. Thus, Claim 4 has a claim limitation with structural language in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held as noted above.

The instant specification teaches a polynucleotide encoding diaminopimelate decarboxylase as SEQ ID NO:11 wherein SEQ ID NO:12 is the encoded amino acid (see Figure 8 description in paragraph [0015]). The specification has fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations (i.e., having diaminopimelate decarboxylase activity). However, the genus of the instant claims also contains polynucleotides within the sequence percent identity limitations, but having different function since a truncated diaminopimelate decarboxylase is no longer required to have the diaminopimelate decarboxylase activity. The specification has not fully described a genus that has sequence percent identity limitations in the absence of functional limitations.

33. Claims 34-36 and 39 are rejected under 35 U.S.C. § 112, first paragraph, enabling deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To make the claimed invention, one of skill in the art is required to make the cells deposited in Claims 34-36 or the vectors of Claim 39.

The specification contains no deposit information for the cells of Claims 34-36. To enable the instant claims by enabling the deposit of the cell strains, the following items are required: (1) the accession number assigned by the depository, (2) the date of deposit, (3) a brief description of the deposit, (4) the name and full address of the depository (37 C.F.R. § 1.801 - 1.809), and (5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative.

The specification contains all the above deposit information required to enable Claim 39. However, the record does not contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01). Upon certifying, the instant rejection of Claim 39 will be overcome.

Summary of Pending Issues

34. The following is a summary of the issues pending in the instant application:

a) The amendment filed December 7, 2004 stands objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure.
b) Claim 4 stands objected to for the plural "polypeptides" in line 4.
c) Claims 17-19 stands objected to for having inconsistent use of language and antecedent indicating language.
d) Claim 30 stands objected to for the comma after the first NRRL number.
e) Claims 1-13, 15-38 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "N-succinylaminoketopimelate transaminase (dapC)".
f) Claims 4-6, 11, 15, 29, and 30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the language "optionally…optionally…and".
g) Claims 5-6 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "comprises **a** P1 promoter element of SEQ ID NO:15" (emphasis added).
h) Claims 7, 9-11, and 26-30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "from a cell of the genus *Corynebacterium*".
i) Claims 26-30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for, the antecedent basis of "said bacterium".
j) Claim 37 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of the phrase "said vector".
k) Claims 2-6, 8-11, and 27-30 stand rejected under 35 U.S.C. § 112, first paragraph, new matter, (at least 80% identity to SEQ ID NO:8 or 12 or 2 or 4).
l) Claims 3-6, 10, 11, 15, 28, 29, and 30 stand rejected under 35 U.S.C. § 112, first paragraph, new matter, (having "thymidilate synthase or 2,3 dihydrodipicolinate N-C6-lyase activity").
m) Claim 25 stands rejected under 35 U.S.C. § 112, first paragraph, new matter, (the limitation of not comprising polynucleotides encoding any (i.e., all) of 5 enzymes).
n) Claims 2-6, 9-11, 13, 15, 27-29, 30 stand rejected under 35 U.S.C. § 112, first paragraph, written description, (truncated ddh polypeptide).
o) Claims 3-6, 10, 11, 15, 28-30 stand rejected under 35 U.S.C. § 112, first paragraph, written description, (a truncated ORF2 polypeptide).
p) Claims 4-6, 11, 15, 29, 30 stand rejected under 35 U.S.C. § 112, first paragraph, written description, (a truncated diaminopimelate decarboxylase polypeptide).

q) Claims 7, 9-11, and 26-29 stand rejected under 35 U.S.C. § 112, first paragraph, written description, based on the limitation of being "from … *Corynebacterium*".
r) Claims 34-36 and 39 stand rejected under 35 U.S.C. § 112, first paragraph, enabling deposit.
s) Claims 1, 2, 4, 7-9, 11-12, 15-23 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Hanke *et al.* (WO 01/49854, published July 12, 2001 – see IDS).
t) Claims 1, 2, 4, 7-9, 11-13, 15-23 stand provisionally rejected under 35 U.S.C. 102(e) as being anticipated by Hanke *et al.* (U.S. Application 09/722,441, now allowed).

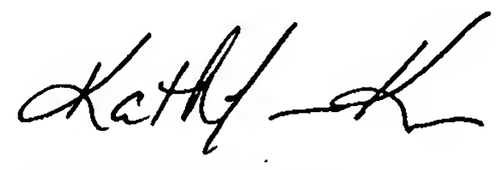
Conclusion

35. Claims 1-13, 15-23, and 25-39 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

March 3, 2005

to Applicant

Help

KEGG ENZYME: 2.6.1.17

Entry EC 2.6.1.17

Name succinyldiaminopimelate transaminase
succinyldiaminopimelate aminotransferase
N-succinyl-L-diaminopimelic glutamic transaminase

Class Transferases
Transferring nitrogenous groups
Transaminases

Sysname N-succinyl-L-2,6-diaminoheptanedioate:2-oxoglutarate $aminotransferase

Reaction N-succinyl-L-2,6-diaminoheptanedioate + 2-oxoglutarate = N-succinyl-2-L-amino-6-oxoheptanedioate + L-glutamate [RN:R04475]

Substrate N-succinyl-L-2,6-diaminoheptanedioate [CPD:C04421]
2-oxoglutarate [CPD:C00026]

Product N-succinyl-2-L-amino-6-oxoheptanedioate [CPD:C04462]
L-glutamate [CPD:C00025]

Comment A pyridoxal-phosphate protein.

Pathway PATH: map00300 Lysine biosynthesis

Ortholog KO: K00821 N-succinyldiaminopimelate aminotransferase

Genes ECO: b3359(argD)
ECJ: JW3322(argD)
ECE: Z4720(argD)
ECS: ECs4210
ECC: c4134(argD)
STY: STY4328(argD)
STT: t4037(argD)
STM: STM3468(argD)
YPK: y1507 y3954(argD)
YPM: YP0172(argD)
YPS: YPTB3731
SFL: SF3378(argD)
SFX: S4385(argD)
ECA: ECA4065(argD)
PLU: plu0394(argD)
BUC: BU534(argD)
BAS: BUsg515(argD)
XFT: PD1474(aspC)
XCC: XCC2218(ybdL)
XAC: XAC2322(ybdL)
VFI: VF2284
PAE: PA3659
PPU: PP1588
PST: PSPTO1531
ACI: ACIAD2080
MCA: MCA1491
NME: NMB0894
NMA: NMA1113
CVI: CV0451(dapC)
RSO: RS04677(dapC)
BPE: BP1765(dapC)
BPA: BPP1996(dapC)
BBR: BB2184(dapC)
NEU: NE2463(dapC)
EBA: ebA6385(dapC)
HPY: HP0624(aspB)
HPJ: jhp0568
HHE: HH0372
WSU: WS1483
DVU: DVU1655
BBA: Bd0127(argD)
ERU: Erum2110(argD)
BJA: blr0615
RPA: RPA0278
BSU: BG12362(yugH)
BHA: BH0936 BH3350
BAN: BA2899 BA5133
BAR: GBAA2899 GBAA5133
BAA: BA_0007 BA_3415
BAT: BAS2700 BAS4771

BCE: BC4035 BC4901
BCA: BCE4102 BCE5040
BLI: BL02594(alaT)
BLD: BLi03320(alaT)
OIH: OB0420
CAC: CAC2380
CPE: CPE1907(patA)
TTE: TTE2440(avtA4)
MTU: Rv0858c
MTC: MT0881
MBO: Mb0881c
MPA: MAP0788c
CGL: NCgl0780(Cgl0814)
CEF: CE0889
NFA: nfa6260
SCO: SCO3658(SCH10.36)
SMA: SAV4517
SYN: sll0938
TEL: tlr0930
GVI: glr3468
ANA: all2340 all4327
AAE: aq_273(aspC4)

Reference 1
Peterkofsky, B. and Gilvarg, C.
N-Succinyl-L-diaminopimelic-glutamic transaminase. J. Biol. Chem.
236 (1961) 1432-1438.

Other DBs IUBMB Enzyme Nomenclature: 2.6.1.17
ExPASy - ENZYME nomenclature database: 2.6.1.17
ERGO genome analysis and discovery system: 2.6.1.17
BRENDA, the Enzyme Database: 2.6.1.17
CAS: 9030-46-0

LinkDB All DBs

=> Original format

[KEGG | DBGET | GenomeNet]